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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/719,258 12/08/00 FRAUENDORFER

F H01.2-9587

000490 HM12/1010
VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA MN 55343-9185

EXAMINER

GOLLAMUDI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/719,258	Applicant(s) FRAUENDORFER, FRIEDEL	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary amendments are acknowledged.

Claims 1-10 are included in the prosecution of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 6- 10 provide for the use of xylose-hardened gelatin capsules, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (5422115) in combination with Acharya (5686094).

Horrobin discloses a method of treating immunological/inflammatory disorders with oral compositions containing omega 3-polyunsaturated fatty acids in a gelatin capsule (see examples). Horrobin teaches several sources for obtaining polyunsaturated fatty acids (fish oil, perilla oil, linseed oil) (col 6, lines 55-66). Horrobin teaches that polyunsaturated acids are used for the treatment of immunological/inflammatory disorders (col 1, line 36-67). Horrobin teaches enteric coating (cellulose acetate phthalate) for the oral composition which would serve to delay of active substance release until the composition reaches the intestines (col 5, line 5-12).

Although Horrobin discloses enteric coating, Horrobin does not teach the use of xylose for the enteric coating.

Acharya discloses a control release formula for oral compositions in several forms such as gelatin capsules. Acharya discloses that release rates are dependent on the structure of the polymeric matrix and modification of the structure with either components hydrocolloids (cellulose derivatives) or complex carbohydrates (xylose)

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control the rate of release. Thus, the release rate may be extended from hours to months. (see col 5/6, line 35 through line 20)

It would have been obvious at the time the invention was made to combine the teachings of Horrobin and Acharya. One would be motivated to do so since both references teach oral compositions with sustained release, Horrobin teaches an oral dosage form for the treatment of immunological/inflammatory disorders and Acharya teaches using xylose to control release rates, yielding an oral dosage form for the treatment of immunological/inflammatory using xylose for sustained release.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin in combination with Acharya, as set forth above and further in view of Morozov et al (5728680).

Horrobin and Acharya as set forth above disclose oral compositions with sustained release.

Acharya teaches the use of xylose for sustained release but does not teach the use of xylose for shell life stability.

Morozov et al teach the use of sugars such as xylose for shell life stability (col 27, line 43-46).

It would have been obvious at the time the invention was made to combine Horrobin and Acharya with Morozov et al Morozov et al provide further motivation for the use of xylose in Horrobin's oral compositions. One would be motivated to use xylose because it not only retards release time but also promotes shell life.

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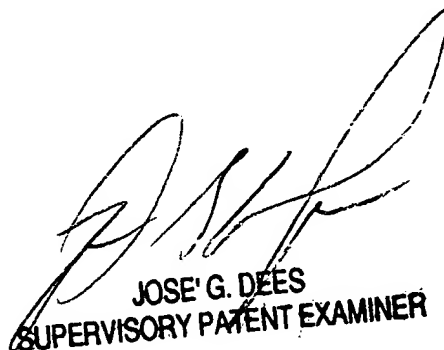
Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

9/24/01


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616